Richard L. Wolgemuth, Ph.D.
Senior Vice President
Global Regulatory Sciences
Pharmaceutical Research Institute

P. O. Box 4000 Princeton, NJ 08543-4000
Tel 609-252-6503 Fax 609-252-7350
Richard.Wolgemuth@bms.com

Bristol-Myers Squibb Company

May 10, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: [Docket No. 2004D–0042] Draft Guidances for Industry on Improving Information About Medical Products and Health Conditions; *Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements* and *"Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms; Federal Register Vol. 69, No. 27, Tuesday, February 10, 2004, pages 6308-09.*

Dear Sir or Madam,

Bristol-Myers Squibb (BMS), a diversified worldwide health and personal care company with principal businesses in pharmaceuticals, infant formulas, and nutritional products, is pleased to have the opportunity to offer comments on two of the "Draft Guidances for Industry on Improving Information About Medical Products and Health Conditions." Our Company's mission is to extend and enhance human life by providing the highest-quality pharmaceutical and related health care products. For these reasons, we are very interested in commenting on the United States Food and Drug Administration (FDA) proposals regarding the disclosure of risk information in consumer-directed print advertisements as well as the use of help-seeking and other disease awareness communications by or on behalf of drug and device firms.

Summary of BMS Comments on Proposal: *Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements*

We support the FDA's proposal to provide guidance in this area and strongly agree that consumer-directed print advertisements for prescription medications should present risk information in consumer-friendly language. Additionally we are pleased to see that the FDA recognizes the value of consumer-directed print advertisements in conveying important information to patients. Research demonstrates that consumer-oriented advertising helps educate patients about medical conditions and treatment options, and encourages dialogue between patients and physicians, prompting large numbers of Americans to discuss illnesses with their health care providers for the first time.

However, there are certain aspects of the proposed guidance that require clarification and/or modification which we have cited below.

2004D-0042 C 23

Specific Comments

- Section 502(n) of the Federal Food, Drug, and Cosmetic Act charges the FDA with the responsibility of regulating the advertising of prescription drugs, including consumer-directed advertisements. 21 U.S.C. 352(n)(3) requires all prescription drug advertisements to contain a "true statement" including "information in brief summary relating to side effects, contraindications, and effectiveness..." This requirement is further defined in the prescription drug advertising regulation at 21 CFR 202.1(e)(1), which requires that an advertisement contain a "true statement of information in brief summary relating to side effects, contraindications . . . and effectiveness." Under 21 CFR 202.1(e)(3)(iii): "The information relating to side effects and contraindications shall disclose *each specific side effect and contraindication* (which include side effects, warnings, precautions, and contraindications and include any such information under such headings as cautions, special considerations, important notes, etc. . . .) contained in required, approved, or permitted labeling for the advertised drug dosage form(s) (emphasis added)."

  We strongly support the use of a consumer-friendly version of the brief summary in consumer-directed print advertisements, as well as the availability of other options proposed in the draft guidance for the presentation of risk information.

  Recommendation: We recommend that the brief summary regulations be amended through appropriate rulemaking procedures to permit the proposed alternative presentations of risk information. This will provide clarity to the industry regarding the appropriate presentation of consumer-friendly risk information in related print advertisements. Furthermore, amendment of the regulations would help create a more predictable regulatory policy and facilitate better industry compliance than the discretionary enforcement approach that is currently proposed in the guidance.

Summary of BMS Comments on Proposal: *"Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms*

We support the FDA's recognition that disease awareness communications can provide important health information to consumers and health care practitioners, and can encourage consumers to seek, and health care practitioners to provide, appropriate treatment. These types of communications help empower patients to play a more active role in managing their own health and may encourage patients to seek treatment for diseases that are currently under-diagnosed and/or under-treated.

However, there are certain aspects of the proposed guidance that require clarification and/or modification which we have cited below.

Specific Comments

- The FDA recognizes, and we concur, that disease awareness communications do not constitute prescription drug labeling or advertising and are not subject to the requirements of the Federal Food, Drug, and Cosmetic Act (the Act) and FDA regulations. Section III. A. of the proposed guidance provides that:

FDA will treat as a "disease awareness communication" any communication by or on behalf of a manufacturer, distributor, or retailer of a drug or device that:

- discuss a disease or health condition;
- if consumer-directed, advise the audience to "see your doctor" for possible diagnosis and/or treatment;
- if aimed at health care practitioners, encourage awareness of signs of the particular disease or health condition, or otherwise provide information to assist in the diagnosis of the particular disease or health condition;
- do not mention a particular drug or device; and
- do not include any representation or suggestion relating to a particular drug or device.

"This kind of communication constitutes neither labeling nor advertising and is not subject to the requirements for the disclosure of risk information and other requirements under the Act....however, there are circumstances in which FDA will treat as labeling or advertising a supposed disease awareness communication...In this situation, or in other situations where a supposed disease awareness communication is determined to, by implication, identify a particular drug or device, the communication can be considered labeling or advertising and can be subject to regulation by FDA."

Help-seeking and disease awareness advertisements may be of greatest value to consumers and health care practitioners for disease states with a new therapeutic option when no or few treatments had previously been available. We respectfully disagree with the exception in Section III. A. that suggests that while being the sole manufacturer of a product does not automatically disqualify a company from disseminating communications that discuss a disease or health condition relating to that product, the FDA could take action against a disease awareness communication in such cases. We are unsure how the guidance can suggest that such communications may be treated as labeling or advertising under the Act when the FDA recognizes that disease awareness communications do not constitute prescription drug labeling or advertising and are not subject to the requirements of the Act and FDA regulations.

Recommendation: We recommend that the FDA remove the proposed sole manufacturer exception detailed in Section III. A. of the draft guidance. This exception could limit the use of appropriate help-seeking and disease awareness communications in a therapeutic area with a "first" treatment option. Such communications could be extremely important for consumers and help address under-diagnosed and/or under-treated diseases.

- The FDA has identified a situation in Section IV. of the draft guidance in which a disease awareness communication may be treated by FDA as labeling or advertising. This situation may arise when a help-seeking or disease awareness communication is presented in combination with reminder promotion or product claim promotion in a way that causes the audience to perceive the two pieces as one advertisement. The draft guidance claims that if these two types of communication are presented in a manner that causes their messages to be linked together by the audience, the failure of the combined communication to include risk and other information required under the Act and FDA regulations would cause the advertised product to be misbranded.

The FDA considers the following factors in determining whether two communications together qualify as promotional labeling or advertising, and therefore must comply with the Act and FDA regulations relating to advertising or labeling:

- Are the pieces perceptually distinct in use of graphic, visual, thematic, or other presentation elements?
- Are the pieces presented in close proximity or temporal proximity?

We are concerned that the second factor is open to interpretation by both the industry and the FDA.

Recommendation: We recommend that the FDA provide specific recommendations in Section IV. of the guidance with regard to proximity or temporal proximity so that it is clear to both the industry and FDA whether two communications together may qualify as promotional labeling or advertising due to proximity relationships. A lack of clarity on this issue would create unnecessary confusion and inconsistency that could impede industry compliance with the FDA's interpretation of this ambiguous standard. We suggest that if no research is available to ground these recommendations, that the FDA sponsor such research and delay implementation of this guidance until the results can be applied to create a more transparent regulatory policy in this area.

Conclusion:
Bristol-Myers Squibb appreciates the opportunity to provide comment and respectfully requests that FDA give consideration to our recommendations.

Sincerely,

Richard L. Wolgemuth

Richard L. Wolgemuth, PhD
Senior Vice President
Global Regulatory Sciences